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10/584,640

05/18/2007

Susan C. Bock

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04/02/2009

Ballard Spahr Andrews & Ingersoll, LLP  
SUITE 1000  
999 PEACHTREE STREET  
ATLANTA, GA 30309-3915

EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

04/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/584,640 | <b>Applicant(s)</b><br>BOCK, SUSAN C. |  |
|                              | <b>Examiner</b><br>HOPE A. ROBINSON  | <b>Art Unit</b><br>1652               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) 50-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/14/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's election with traverse of Group I (claims 1-49) is acknowledged.
2. The traversal is on the grounds that unity of invention exists, the cited art does not break unity and that there is no search burden. Applicant is reminded that burden of search is not germane in the lack of unity practice, thus this argument is moot. With respect to the lack of unity argument presented by the examiner, the requirement is maintained and made final because as previously stated and set forth in the instant office action the claimed invention does not escape the prior art and therefore lacks unity of invention.

### ***Claim Disposition***

3. Claims 1-82 are pending. Claims 1-49 are under examination. Claims 50-82 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.
4. The Amendment filed on September 13, 2005 has been received and entered.

### ***Specification***

5. The specification is objected to because of the following informalities:

The specification is objected to because the title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following is suggested: "Method of decreasing Thrombosis or Coagulation in a System".

Correction is required.

### ***Drawing***

6. The drawing filed on September 13, 2005 is accepted by the examiner.

### ***Claim Objection***

7. Claims 1, 3, 7, 23, 38 and 40 are objected to because of the following informalities:

Claim 1 is objected to because the acronym ATIII does not have the corresponding spelled out meaning. See also claims 23 and 38.

Claim 3 is objected to because the claim does not further limit claim 1.

Claim 7 is objected to because the claim is missing the article "a" in front of the word "stent".

Claim 40 is objected because the following typographical error appears, "wherein the wherein the".

Correction is required.

***Information Disclosure Statement***

8. The Information Disclosure Statement filed on October 14, 2008 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action. Note however that the references listed on the list entitled "IDS Prosecution Document Cover Sheet" have been lined through. The attorney document number appears and isn't material for printing on the face of the patent. In addition, applications when listed on the 1449 form is considered in its entirety, thus it is not necessary to indicate "claims" or "certificate of correction" or "search notes" or "first office action" because as a result application 10/014,658 is listed 13 times on the form and only needs to be reported once on the face on the patent (several other duplicates are on the IDS). The references have been considered however are lined through because they are not presented in proper format, they have not been considered. Applicant is urged to resubmit the PTO-1449 in the right format.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 6, 17, 32 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a method of decreasing coagulation or thrombosis via administration of an ATIII molecule. Claims 6, 17, 32 and 48 encompass any medical device, biomaterial, insect or yeast.

The instant specification does not demonstrate possession of the large genus of medical device, biomaterial, insect or yeast encompassed in the claim language. The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the

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claimed genus. Moreover, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 1 is indefinite because no steps are provided to determine shear wall conditions and it is noted that claim 2 indicates it has to be determined. See also claims 23 and 38 with the same language. The dependent claims hereto are also included.

Claim 2 is indefinite because it is unclear how the determination will occur because no steps are provided in the method for said determination.

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Claims 9-12, 25-28 and 41-44 lack clear antecedent basis for "the dissociation constant of ATIII".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 4-7, 23 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Bock et. al. (U.S. Patent No. 6,878,813, May 12, 1998).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.



The broadest reasonable interpretation of the instant claim 1 is a method of decreasing coagulation or thrombosis comprising the administration of ATIII, because the "wherein clause" are not actual method steps but appear to be resulting effects of said administration. Therefore, said administration of ATIII results in an increased affinity for heparin or heparan sulfate proteoglycans bound to a solid surface (the high wall shear rate condition is not recited as a method step, but as an effect of the binding which occurs as a result of the administration of heparin or heparan sulfate proteoglycans).

Bock et al. teach the administration of ATIII to affect reduction in thrombosis and coagulation to treat blood clotting disorders. Bock et al. teach the use of an AT III with enhanced heparin affinity (see claim 11 and paragraph 22 and columns 1-4 of the patent for example). Therefore, as ATIII is administered and the reference teaches enhancement in binding affinity with heparin, the resulting shear rate is an inherent property. Moreover, Bock et al. teach that administration of the modified AT III (with enhanced heparin affinity) can be used as a medicament for acute respiratory distress syndrome, restenosis, stroke, thrombosis, sepsis, trauma, thrombosis associated with cardiopulmonary by pass or joint replacement, recursion, disseminated intravascular coagulopathy, ischemic stroke and wherein AT III is provided in bodily fluids etc., thus, said administration of ATIII is done under high wall shear rate conditions (see columns 5-6). Based on the diseases/disorders treated with AT III claims 4-7 are anticipated since medical device, catheter, graft or stent is necessary in the treatment regimen. Therefore the limitations of the claims are met by the reference.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Church et al. (U.S. 6,207,419, March 27, 2001 ).

The broadest reasonable interpretation of the instant claim 1 is a method of decreasing coagulation or thrombosis comprising the administration of ATIII, because the "wherein clause" are not actual method steps but appear to be resulting effects of said administration. Therefore, said administration of ATIII results in an increased affinity for heparin or heparan sulfate proteoglycans bound to a solid surface (the high wall shear rate condition is not recited as a method step, but as an effect of the binding which occurs as a result of the administration of heparin or heparan sulfate proteoglycans).

Church et al. teach Therefore, as ATIII is administered and the reference teaches enhancement in binding affinity with heparin, the resulting shear rate is an inherent property. Therefore the limitations of the claim are met by the reference.

### ***Conclusion***

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652

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